

**SPECIFICATION****TITLE****"DETECTION OF DIASTOLIC HEART FAILURE"****BACKGROUND OF THE INVENTION****5    Field of the Invention**

The present invention relates to an implantable medical apparatus for detecting diastolic heart failure (DHF), of the type having a DHF determining device for determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient. The invention also relates to a pacemaker  
10 provided with such an apparatus, and a method of detecting DHF, including the step of determining at least one blood pressure parameter for detecting a DHF state of the heart of a patient.

**Description of the Prior Art**

There is a growing recognition that congestive heart failure caused by  
15 a predominant abnormality in the diastolic function, i.e. diastolic heart failure, DHF, is both common and causes significant morbidity and mortality. Therefore early detection of DHF is important. Patients do not, however, seem to have symptoms at an early stage. In addition it has been hard to separate diastolic and systolic heart failure and they may also exist  
20 simultaneously.

It has been discovered that among the few parameters, separating diastolic heart failure from systolic heart failure, are certain blood pressure parameters obtained during work of the patient. Thus United States Patent No. 6,438,408 describes an implantable medical device for monitoring  
25 congestive heart failure, CHF. A number of heart failure parameters indicative of the state of the heart failure are measured employing EGMs, blood pressures including absolute pressures, developed pressures (= systolic pressures – diastolic pressures) and the time derivative  $dP/dt$ , as well as heart chamber volumes. One of these parameters is the relaxation or contraction  
30 time constant  $\tau$  of the heart chamber. This constant  $\tau$  is calculated from a

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continuous pressure signal and is the drop in ventricular pressure at the end of systole and in the first part of diastole. The  $\tau$  parameter is thus a general parameter reflecting the relaxation process.

5           Thus with the present invention the reduced peak and submaximal exercise performance of DHF patients is utilized for detecting DHF. With the technique according to the invention it is possible to detect DHF at an early stage, often before the patient seem to have any symptoms.

10           In the present invention the workload situation of the patient must be identified, and therefore, in an embodiment of the apparatus according to the invention, an activity sensor is provided for determining the workload of the patient.

15           In another embodiment of the apparatus according to the invention an averaging unit is provided to form an average value of pulse pressures during a plurality of cardiac cycles with the workload situation and an average value of pulse pressures measured during a number of cardiac cycles with the patient in rest. In this way the quality of the pulse pressure measurements is improved.

20           In other embodiments of the apparatus according to the invention a wireless communication unit is connected to the comparison unit for automatically sending the results of the comparison of measured pulse pressures with the reference values to an external receiver, or a memory is provided for storing the results of the comparison of measured pulse pressures with the reference values. Thus if the pulse pressure has risen  
25 above the reference value in a predetermined way this condition is automatically transmitted to a physician or stored for transmission in connection with a follow-up.

30           In other embodiments of the apparatus according to the invention, the pressure measuring unit includes a pressure sensor adapted for placement in right ventricle or coronary veins of the patient's heart, and the pressure measuring unit determines the maximum and minimum pressures in a cardiac cycle. It is preferred to place the pressure sensor in the right ventricle or the

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coronary veins, since the pressures in these places reflect the morphology of the left ventricular or aortic pulse pressure, especially with regard to maximum and minimum pressures.

The invention also relates to a pacemaker provided with the apparatus  
5 for detecting DHF and a control that optimizes pacing therapy depending on the result of the comparison of the measured pulse pressures with the predetermined reference values. The pressure measuring unit of the apparatus according to the invention then preferably includes a pressure sensor connected to the pacemaker, since it can monitor the pulse pressure  
10 of its carrier for long periods. This is an advantage since evolvement of DHF is a slow process.

In embodiment of the pacemaker according to the invention, a rate responsive sensor issued as an activity sensor for determining the workload situation of the patient. Even the pressure sensor of the pacemaker can be  
15 used as activity sensor.

In an embodiment of the method according to the invention, photo-plethysmographic signals are sensed for determining the pulse pressure, since it has been discovered that photo-plethysmographic signals obtained by a sensor placed close to the tissue where a pacemaker or ICD is implanted  
20 contain information about pulse pressure.

As mentioned above the measured pulse pressure is compared with a predetermined reference value, and in an embodiment of the apparatus and the method according to the invention the pulse pressure in a cardiac cycle is measured for a predetermined workload situation and a rest situation of the  
25 patient, and the difference between the pulse pressures measured in the workload and rest situations is compared with a predetermined reference value for the difference for DHF detection. A condition of DHF is identified by a higher pulse pressure during workload than a patient with a systolic heart failure would have. The reference value for detection of DHF is preferably  
30 obtained from measurements on the patient at an early stage of the implantation period of the apparatus or pacemaker. The patient is assumed not to suffer from DHF at the time of implantation. Therefore, in an

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embodiment of the method according to the invention, pulse pressures are measured for different workloads of the patient and for the patient in rest at an early time, when the patient is not suffering from DHF, for determining the reference values. These pulse pressures from an early stage can also be  
5 measured for a certain period of time and typical pulse pressures during an identified workload and during rest are gathered and averaged and then stored for later use as reference values for comparison purposes. If later the measured pulse pressure, or average pulse pressure measured during several cardiac cycles, exceeds the reference value determined in this way by  
10 a prescribed amount x%, this is used as an indication of DHF.

In the following an embodiment of the invention using a pressure sensor will be described, and the term pulse pressure means the varying  
15 pressure in aorta during a cardiac cycle.

The above-mentioned pulse pressure can be obtained from the pressure measured in the left ventricle. In Figure 1 the top curve shows the left ventricular pressure and the curve below the aortic pressure as a function of time. The magnitude of the pressures are indicated in arbitrary units in  
20 Figure 1.

The asterisks in the curves of Figure 1 denote time points for the maxima and minima of the time derivative of the left ventricular pressure,  $dLVP/dt_{max}$  and  $dLVP/dt_{min}$  respectively. As the aortic valves open close to the point  $dLVP/dt_{max}$ , the aortic pressure is close to the left ventricular  
25 pressure at this point of time.

During the period from  $dLVP/dt_{max}$  to  $dLVP/dt_{min}$  blood flows into aorta. The maximum of aortic pressure is situated in this period. The pulse pressure consequently can be obtained from the left ventricular pressure by subtracting the pressure at the point of  $dLVP/dt_{max}$  from the maximum of the left  
30 ventricular pressure obtained during the mentioned period.

If the conditions are such that pressure signals from other parts of the hemodynamic system are morphologically similar to the left ventricular

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pressure, these signals can also be used for determining the pulse pressure in the present invention, since only relative changes have to be determined for detecting DHF.

Figure 2 shows an embodiment of a pacemaker according to the invention comprising basic pacemaker circuits 20. A pressure sensor 2 is located in the right ventricle 18 of a patient's heart and connected to the pacemaker 4. The signals from the pressure sensor 2 are supplied to an A/D-converter 10. After A/D-conversion the time derivative of the signal is formed in a derivation unit 16. The time derivative of the pressure signals are filtered in the low pass filter 12 before supply to the microprocessor and supporting circuits 14. Since time derivation promotes high frequency noise, it is advisable to eliminate in this way possible false peaks and valleys, which could be interpreted as  $dLVP/dt_{\max}$  and  $dLVP/dt_{\min}$ . The filtered signals are supplied regularly into a microprocessor and supporting circuits 14.

Located in the pacemaker 4 is an activity sensor 6 that is connected to an activity measuring unit 8 for determining the workload of the patient. A corresponding activity or workload signal is fed to the microprocessor and supporting circuits 14.

Figure 3 is a flow chart illustrating an example of the overall process for collecting pulse pressure data. The development of DHF is a slow process as mentioned. A timer, at 26 in Figure 3, is therefore provided for activating pulse pressure measurements on a regular basis for reducing the current drain and releasing microprocessor power.

Collection of pulse pressure data is performed for different workloads of the patient, at 22 in Figure 3. As mentioned above the collection process is activated by a timer, at 26, and therefore the process has to wait for activation by the timer before starting, at 24. As the process is started, at 28, pulse pressure data are stored in different intermediate memory locations depending on the workload of the patient, at 30. Addresses to this memory locations are obtained from a table pointed to by the workload or activity measuring unit depending on the workload or activity, at 32. Pulse pressure data from the intermediate memory is then stored in another memory

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according to the address obtained in the preceding step for later analysis, at 34.

To improve the accuracy of the data stored the procedure of storing pulse pressure data can be performed by forming a floating mean value. One way to do this is to add a fraction  $1/k$  of a new pulse pressure value  $P(i)$  to the pulse pressure value stored  $P_{\text{stored}}$  at the memory location pointed to by the activity measuring unit and form a mean value  $P_{\text{store}}$  according to the following equation

$$P_{\text{store}} = \frac{P(i) + P_{\text{stored}} \times (k - 1)}{k}$$

Figure 4 is a flow chart illustrating in greater detail the procedure for obtaining the pulse pressure.  $P_{\text{max}}$  and  $P_{\text{min}}$  denote temporary storages of maximum and minimum aortic pressures.

In order to start the pulse pressure measurements a QRS has to be detected, at 38 in Figure 4, after reset of  $P_{\text{max}}$  and  $P_{\text{min}}$ , at 36. Pressure samples  $P(i)$  are then stored continuously together with the time derivative  $dP(i)/dt$  for comparison, at 40. A certain number of contiguous samples have to exist simultaneously, so that the above-mentioned filtering of the time derivative of the pressure is in accordance with the length of the filter coefficients. Care must be taken so that the delay in the filter influences the selection of corresponding pressure samples in a timely fashion, i.e. the pressure samples are selected with the same delay.

When  $dP/dt_{\text{max}}$  has been found, at 42 and 44, the pressure at that point in time is selected as the minimum pressure  $P_{\text{min}}$ . The pressure then rises in the aorta and the maximum pressure during systole occurs in the period between  $dP/dt_{\text{max}}$  and  $dP/dt_{\text{min}}$ , cf. the description of Figure 1. In the process illustrated in Figure 4 a simplified approach is used for determining maximum pressure  $P_{\text{max}}$ . Instead of determining the point of time for  $dP/dt_{\text{min}}$  a timer is started at the point of  $dP/dt_{\text{max}}$ , at 46 in Figure 4 and  $P_{\text{max}}$  is determined according to steps 48, 50, 52, 54 till timer overflow, at 56. Such a timer procedure is justified since the systolic time period in practice varies little. The

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pulse pressure is then obtained by subtracting  $P_{\min}$  from  $P_{\max}$ , at 58, which is the output of the process.

5 Instead of determining the pulse pressure with pressure sensors, it can be determined by photo-plethysmography. Photo-plethysmographic signals from a sensor placed close to the tissue at the location of the implanted pacemaker or ICD contains information on pulse pressure. Thus such photo-plethysmographic signals can be used as an alternative for determining the pulse pressure.

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